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AMENDMENTS TO LB 221

1. Strike original sections 2 and 3 and insert the following new sections:

"Sec. 2. Section 71-5408, Reissue Revised Statutes of Nebraska, is amended to read:

~~71-5408.~~ Sections ~~71-5401 to 71-5408~~ 71-5402 to 71-5407 and sections 2, 3, and 10 of this act shall be known and may be cited as the Nebraska Drug Product Selection Act.

Sec. 3. The purposes of the Nebraska Drug Product Selection Act are to provide for the drug product selection of equivalent drug products and to promote the greatest possible use of such products.

Sec. 4. Section 71-5402, Revised Statutes Supplement, 2002, is amended to read:

71-5402. ~~As used in~~ For purposes of the Nebraska Drug Product Selection Act, unless the context otherwise requires:

(1) Authorized transmitted copy means a paper copy of a written, signed medical order issued by a practitioner authorized to prescribe which is produced by an electronic or electromagnetic transmission or other means as authorized by rule and regulation of the department upon recommendation of the board;

(2) Bioequivalent means drug products: (a) That are legally marketed under regulations promulgated by the federal Food and Drug Administration; (b) that are the same dosage form of the identical active ingredients in the identical amounts as the drug

product prescribed; (c) that comply with compendial standards and are consistent from lot to lot with respect to (i) purity of ingredients, (ii) weight variation, (iii) uniformity of content, and (iv) stability; and (d) for which the federal Food and Drug Administration has established bioequivalent standards or has determined that no bioequivalence problems exist;

(3) Board means the Board of Pharmacy;

(4) Brand name means the proprietary or trade name selected by the manufacturer, distributor, or packager for a drug product and placed upon the labeling of such product at the time of packaging;

(5) Chemically equivalent means drug products that contain amounts of the identical therapeutically active ingredients in the identical strength, quantity, and dosage form and that meet present compendial standards;

(6) Department means the Department of Health and Human Services Regulation and Licensure;

(7) Drug product means any drug or device as defined in section 71-1,142;

(8) Drug product select means to dispense, without the practitioner's express authorization, an equivalent drug product in place of the brand name drug product contained in a medical order of such practitioner;

(9) Equivalent means drug products that are both chemically equivalent and bioequivalent;

(10) Generic name means the official title of a drug or drug combination as determined by the United States Adopted Names

Council and accepted by the federal Food and Drug Administration of those drug products having exactly the same active chemical ingredients in exactly the same strength and quantity;

(11) Medical order has the definition found in section 71-1,142;

(12) Pharmacist means a pharmacist licensed under the Uniform Licensing Law; and

(13) Practitioner has the definition found in section 71-1,142.

~~Brand name means the proprietary or trade name selected by the manufacturer, distributor, or packager for a drug and placed upon its container, label, or wrapping at the time of packaging;~~

~~(2) Generic name means the official title of a drug or drug combination as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration of those drug products having exactly the same active chemical ingredients in exactly the same strength and quantity;~~

~~(3) Drug product select means to dispense, without the duly licensed prescriber's express authorization, a chemically equivalent and bioequivalent drug product in place of the drug product ordered or prescribed;~~

~~(4) Chemically equivalent means drug products that contain amounts of the identical therapeutically active ingredients in the identical strength, quantity, and dosage form and that meet present compendial standards;~~

~~(5) Bioequivalent means drug products that:~~

~~(a) Are legally marketed under regulations promulgated by~~

~~the federal Food and Drug Administration;~~

~~(b) Are the same dosage form of the identical active ingredients in the identical amounts as the drug product prescribed;~~

~~(c) Comply with compendial standards and are consistent from lot to lot with respect to (i) purity of ingredients, (ii) weight variation, (iii) uniformity of content, and (iv) stability; and~~

~~(d) For which the federal Food and Drug Administration has established bioequivalent standards or has determined that no bioequivalence problems exist;~~

~~(6) Pharmacist means a pharmacist duly licensed in accordance with the Uniform Licensing Law;~~

~~(7) Medical practitioner has the same meaning as practitioner in section 71-1,142; and~~

~~(8) Department means the Department of Health and Human Services Regulation and Licensure.~~

Sec. 5. Section 71-5403, Revised Statutes Supplement, 2002, is amended to read:

71-5403. (1) A pharmacist may drug product select except when:

(a) A practitioner designates that drug product selection is not permitted by specifying in his or her own handwriting on the face of the prescription or by telephonic or electronic communication that there shall be no drug product selection. For written prescriptions, the practitioner shall specify on the prescription the phrase "no drug product selection," "dispense as

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written," "brand medically necessary," or "no generic substitution" or the notation "N.D.P.S.," "B.M.N.," or "D.A.W." or words or notations of similar import to indicate that drug product selection is not permitted. The pharmacist shall note "N.D.P.S." or "No Drug Product Selection" on the face of the prescription to indicate that drug product selection is not permitted if such is communicated orally by the prescribing practitioner; or

(b) A patient or representative or caregiver of such patient instructs otherwise.

(2) A pharmacist shall not drug product select a drug product unless:

(a) The drug product, if it is in solid dosage form, has been marked with an identification code or monogram directly on the dosage unit;

(b) The drug product has been labeled with an expiration date;

(c) The manufacturer, distributor, or packager of the drug product provides reasonable services, as determined by the board, to accept the return of drug products that have reached their expiration date; and

(d) The manufacturer, distributor, or packager maintains procedures for the recall of unsafe or defective drug products.

~~Except as limited (a) by this section, when a medical practitioner designates that no drug product selection is permitted, and (b) by subsection (1) of section 71-5404, unless the purchaser instructs otherwise, the pharmacist may drug product select a drug product with the same generic name in the same strength, quantity, dose,~~

~~and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, bioequivalent, except that products designated as controlled substances as listed in Schedule I of section 28-405 shall not be interchanged. It shall be the responsibility of the purchaser or the ultimate user to advise or instruct the pharmacist that he or she does not desire drug product selection, and it shall not be mandatory for the pharmacist to drug product select against his or her professional judgment.~~

~~(2) The department may adopt and promulgate necessary rules and regulations, upon the joint recommendation of the Board of Medicine and Surgery and the Board of Pharmacy, relating to (a) bioavailability, (b) fraudulent or misleading advertising pertaining to drug product selection, and (c) the control of conditions in which the prescribing practitioner or purchaser should be advised when drug product selection has been made by the pharmacist.~~

~~(3) A medical practitioner duly authorized to prescribe drugs, medicinal substances, or controlled substances may specify in writing or by telephonic communication on each prescription that there shall be no drug product selection for the specified brand name drug in any prescription. The phrase no drug product selection or the notation N.D.P.S. shall be specified on the prescription form or orally communicated by the medical practitioner. The pharmacist shall note N.D.P.S. on the face of the prescription if such is communicated orally by the prescribing medical practitioner.~~

~~(4) Each pharmacy shall post a sign in a location easily~~

~~seen by patrons at the counter where prescriptions are dispensed stating that this pharmacy may be able to select a less expensive drug product which is bioequivalent to the one prescribed by the prescriber unless the purchaser does not approve. The sign shall be provided by the department, at a cost to the pharmacy which shall not exceed the actual cost of printing to the department, and the printing on the sign shall be in block letters not less than one inch in height.~~

~~(5) A pharmacist shall not drug product select a product under the provisions of this section unless: (a) The product, if it is in solid dosage form, has been marked with an identification code or monogram directly on the dosage unit; (b) the product has been labeled with an expiration date; (c) the manufacturer, distributor, or packager provides reasonable services to accept return products that have reached their expiration date; and (d) the manufacturer, distributor, or packager maintains recall capabilities for unsafe or defective drugs.~~

~~(6)(a) Except as provided in subdivision (b) of this subsection, a pharmacist shall not drug product select a product under this section that is:~~

~~(i) An enteric-coated tablet or capsule;~~

~~(ii) An injectable suspension other than an antibiotic or insulin;~~

~~(iii) A controlled-release product;~~

~~(iv) A suppository containing active ingredients for which systemic absorption is necessary; or~~

~~(v) A different delivery system for aerosol and nebulizer~~

~~drugs.~~

~~(b) A pharmacist may drug product select a product set forth in subdivision (a) of this subsection if such product has been determined by the Food and Drug Administration to be bioequivalent and therapeutically equivalent to the prescribed drug.~~

~~(7) The department shall maintain a list of drug products for which bioequivalency has been demonstrated and documented either federally or by the state.~~

Sec. 8. Section 71-5406, Revised Statutes Supplement, 2002, is amended to read:

71-5406. The manufacturer, packager, or distributor of any ~~human use~~ legend drug sold, delivered, or offered for sale for human use in the State of Nebraska ~~after January 1, 1978,~~ shall have the name and address of the manufacturer of the finished dosage form of the drug printed on the label on the ~~immediate container of the drug the name and address of the manufacturer of the finished dosage form of the~~ container of such drug. Whenever a duly authorized agent of the department ~~finds or~~ has probable cause to believe that any drug is without such labeling, the agent shall embargo such drug and shall affix ~~thereto~~ an appropriate marking~~,~~ ~~giving~~ thereto. Such marking shall contain: (1) Adequate notice that (a) the drug is or is suspected of being sold, delivered, or offered for ~~gain~~ sale in violation of the Nebraska Drug Product Selection Act and (b) has been embargoed; and (2) a ~~,~~ ~~and~~ warning that it is unlawful for any person to remove or dispose of the embargoed drug by sale or otherwise without the permission ~~from~~ of

the agent or a court of competent jurisdiction.

Sec. 10. The department may adopt and promulgate rules and regulations necessary to implement the Nebraska Drug Product Selection Act upon the joint recommendation of the Board of Medicine and Surgery and the Board of Pharmacy.

Sec. 12. The following section is outright repealed: Section 71-5401, Reissue Revised Statutes of Nebraska.".

2. On page 9, line 3, strike "verbally" and insert "orally".

3. On page 10, line 10, strike "made" and show as stricken; in line 11 strike "in" through "and", show as stricken, and insert "pursuant to the act or"; in line 12 strike "that" through "promulgate", show as stricken, and insert "adopted and promulgated"; in line 14 after "within" insert "the"; in line 17 strike "in accordance with", show as stricken, and insert "under"; strike beginning with "In" in line 19 through the second "the" in line 20, show as stricken, and insert "The"; and in line 28 strike "the provisions", show as stricken, and insert "any provision".

4. On page 11, line 2, strike "such" through "be", show as stricken, and insert "the act is"; in line 4 strike "shall be", show as stricken, and insert "is" and strike "an" and show as stricken; in line 7 strike "the", show as stricken, and insert "a"; and in line 9 after "Original" insert "section 71-5408, Reissue Revised Statutes of Nebraska, and" and after the second comma insert "71-5406,".

5. Renumber the remaining sections accordingly.